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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,274	KAKIUCHI, TOSHIHIKO	
	Examiner	Art Unit	
	GiGi Huang	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The amendment filed 09/04/2007 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 1-4 and 6 have been amended.

(B) Claim 5 has been cancelled.

(C) Claims 7-11 has been added.

(D) Comments regarding Office Action have been provided drawn to:

a. 102 (b) rejection, of Yazawa et al., has been maintained for the reasons of record.

b. 102 (b) rejection, of Kiliaan et al., has been maintained for the reasons of record.

c. 102 (b) rejection, of Bruzzese, has been maintained for the reasons of record.

d. 112, First Paragraph rejection for claims 1-6, which have been withdrawn for the reasons of record.

e. 112, Second Paragraph rejection for claims 5 and 6, which have been withdrawn for the reasons of record.

f. Information Disclosure Statement has been considered and an annotated copy has been submitted for JP-4-226915-A and JP-2000-510006-A. Only the abstract for JP-2001-122791-A had been previously

annotated and remains so as Applicant has stated that is the relevant portion of the document.

2. Amendments to claims 1-4 and dependent claim 6 are subject to a new matter rejection. Details are enclosed in the body of the office action.

3. Amendments to claims 1-4 and 6 are subject to as 112, Second Paragraph rejection. Details are enclosed in the body of the office action.

4. Amendments to claim 6 are subject to as 112, Second Paragraph rejection. Details are enclosed in the body of the office action.

5. Newly added claim 10 is subject to a new matter rejection. Details are enclosed in the body of the office action.

6. Newly added claim 10 is subject to as 112, Second Paragraph rejection. Details are enclosed in the body of the office action.

7. Newly added claim 11 is subject to as 112, Second Paragraph rejection. Details are enclosed in the body of the office action.

8. Newly added claims are subject to a 102(b) rejection. Details are enclosed in the body of the office action.

9. Claims 1-4 and 6-11 are pending in the case.

10. Claims 1-4 and 6-11 are present for examination.

11. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1- 6 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic treatment, does not reasonably provide enablement for prophylactic prevention of varicose veins. Applicant has cancelled claim 5 and amended the claims to delete the recitations of "prevention" and "prophylactic" form the claims. The rejection has been withdrawn.

14. Claims 1 and 3 and all dependent claims 2,4, and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection to the newly amended claims 1 and 3 and all dependent claims 2,4, and 6.

Claims 1 and 3 and all dependent claims 2,4, and 6, now draw to a composition that does "not contain any one of elements selected form the group consisting of phospholipids, compounds which are a factor in methionine metabolism, and 10-40% by weight of antioxidant/reducing vitamins or provitamins".

There is support for the negative recitation of phospholipids in the specification but there is no support for the negative recitation of compounds which are a factor in

methionine metabolism, and 10-40% by weight of antioxidant/reducing vitamins or provitamins" in the specification.

The term "compounds which are a factor in methionine metabolism" fail to be properly described in the specification to in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is directed to reach through claim language as the term is addressing compounds by what it *does* rather than what the compounds *are*.

It is noted that the claims as amended are in Markush language will be interpreted as so thereby, the composition would not contain any *one* of elements selected from the *group consisting of* "phospholipids, compounds which are a factor in methionine metabolism, and 10-40% by weight of antioxidant/reducing vitamins or provitamins". As a result, wherein a composition would contain phospholipids but not 10-40% by weight of antioxidant/reducing vitamins or provitamins; or a composition would not contain phospholipids but did have 10-40% by weight of antioxidant/reducing vitamins or provitamins, it would fulfill the limitations of the claims as written.

Claims 1 and 3 and all dependent claims 2,4, and 6 are thereby rejected on the grounds of new matter and written description.

15. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had

possession of the claimed invention. This is a new matter rejection to the newly added claim 10.

Claim 10 draw to a composition of eicosapentaenoic acid and "an additive selected from the group consisting of food, a dietary supplement, a cosmetic, or a quasi drug". It is unclear how food, a dietary supplement, a cosmetic, or a quasi drug is an *additive* to a composition verses *being* the composition as directed in the specification.

There is no support in the specification for how food, a dietary supplement, a cosmetic, or a quasi drug is an *additive* to a composition verses *being* the composition in the specification. The term "the composition consists essentially of eicosapentaenoic acid an additive selected from the group consisting of food, a dietary supplement, a cosmetic, or a quasi drug", fail to be properly described in the specification to in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 10 is thereby rejected on the grounds of new matter and written description.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

17. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "compounds which are a factor in methionine metabolism" fail to be properly described in the specification to in a way as to reasonably convey to one skilled in the relevant art and is thereby unclear for one of skill in the art to determine the metes and bounds of the invention.

18. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a composition of eicosapentaenoic acid and "an additive selected from the group consisting of food, a dietary supplement, a cosmetic, or a quasi drug". It is unclear how food, a dietary supplement, a cosmetic, or a quasi drug is an *additive* to a composition verses *being* the composition as directed in the specification. One skilled in the relevant art would not be able to determine the metes and bounds of the invention.

19. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a composition that *consists essentially of* eicosapentaenoic acid and "an additive selected from the group consisting of food, a dietary supplement, a cosmetic, or a quasi drug". It is unclear how the specific recitation of *consists essentially of eicosapentaenoic acid* would apply if the additive is food, a dietary supplement, a cosmetic, or a quasi drug as each and every additive listed would drastically change the composition that it to *consists essentially of eicosapentaenoic acid*. One skilled in the relevant art would not be able to determine the metes and bounds of the invention.

20. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a therapeutic agent that "consists essentially of eicosapentaenoic acid as it effective component and a pharmaceutically acceptable carrier". However, if the stabilizer is an antioxidant that would be necessary as EPA is a fatty acid and prone to oxidation, this could affect the overall composition, as antioxidant can be an active agent as well as an excipient. One skilled in the relevant art would not be able to determine the metes and bounds of the invention.

21. Claim 6 recites the limitation "A method for treating varicose veins of lower extremities" in claim 3. There is insufficient antecedent basis for this limitation in the claim. Claim 3 is a composition claim not a method claim for which claim 6 recites for varicose veins.

22. Claims 5 and 6 were rejected for the recitation of the "use of eicosapentaenoic acid in the manufacture of" and "method for preventing and treating....by using eicosapentaenoic acid" as it did not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Applicant has cancelled claim 5 and amended claim 6 to depend from claim 3 and recite the oral administration for treating varicose veins of lower extremities. The rejection is withdrawn.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Yazawa et al. (EP 0,404,300).

Yazawa et al. teaches a phospholipid composition comprising eicosapentaenoic acid and a method of making.

Yazawa et al. teaches an EPA-containing phospholipid composition made by utilizing microorganisms to produce eicosapentaenoic acid (EPA) and several methods of fractionation to purify the EPA-containing phospholipids for formulation (Abstract, Page 2, lines 1-5).

The EPA-containing phospholipids can be used in many formulations, including foodstuffs, cosmetics, pharmaceuticals, agriculture, fishing, and chemical industries. Preferable formulation forms were capsules, granules, pills, suspensions, emulsions, powders, tablets, syrup, and injectable liquids with pharmaceutical or biological acceptable additives (Abstract, Page 2, lines 1-9, 27-38, 40-55, Page 3, lines 1-15, 34-60, Page 4, lines 1-12, 20-29).

The composition was also envisioned as a pharmaceutical treatment of disease (i.e. human, pets, animals), an animal feed, a health food, and a lipid metabolism modifier (supplement/health food) (Abstract, Page 2, lines 27-38, 40-55, Page 3, lines 1-

15, 34-60, Page 4, lines 1-12, 20-29, Table 1, Page 6, Examples 2 and 3, lines 20-56, Claims 1 and 9).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

25. Claims 7-11 rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 01/84961).

Kiliaan et al. teaches a composition comprised of long chain polyunsaturated fatty acids, preferably eicosapentaenoic acid, for use of vascular disorders.

Kiliaan et al. teaches the composition to have best results when EPA is mixed with docosahexaenoic acid (DHA) for the long chain polyunsaturated fatty acids, but allows for them to be utilized singularly (claims 1, 4 and 5). The composition can be a dietetic, pharmaceutical, and a nutritional preparation.

The product forms could be a liquid, powder, bar, cookie, sweet, concentrate, paste, sauce gel, emulsion, tablet, capsule for providing a daily dose either as a single or multiple dose form. The products would be packaged by methods know in the art to keep the products fresh for easy use, administration, and shelf life (Abstract, Page 5, lines 23-32, Page 6, lines 1-9, 24-28).

Examples of the compositions are taught including, capsules (EPA at 75 mg, Page 13, Example 1), pudding (EPA at 30mg, Page 13, Example 2), powdered concentrate for use inn drinks (EPA about 150mg, Page 14, Example 3), and muesli-bar/food (EPA about 60mg, Page 14 and 15, Example 5).

The uses for the compositions are for the treatment of vascular, cardio-and cerebrovascular disorders and a selected range of secondary problems. Specific cardiovascular problems that were addressed were thrombi, vascular accidents, atherosclerosis, and varicose veins/varices (Page 11, lines 28-30, Page 12, lines 9-14).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

26. Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruzzese (U.S. Pat. # 5,776,978).

Bruzzese teaches a composition comprising EPA and/or DHA in their fatty acid, ester, and salts forms for use in the prevention and/or treatment of arthrosclerosis, nervous system, cardiovascular, skin, and malignant pathologies (Abstract, Col. 1, lines 5-22).

Bruzzese teaches compositions comprised of EPA esters or EPA ethylesters, 10-40% by weight of antioxidant/reducing vitamins or provitamins, and no specific mention of compounds for methionine metabolism. Examples included DHA esters and ethylesters. Bruzzese teaches that it is understood that DHA and EPA in any of the form taught can be used individually or as a mixture of the two. The mixtures can be prepared by combining the desired quantities of the purified forms or the mixtures of the desired esters or salts thereof (Col 1, lines 5-15, 27-35, 39-47, Col. 3, Table 1, Col. 5, Example 4, Col. 6, Example 5 and 6, Claims 1-7).

Bruzzese also taught the use of these compositions for cardiovascular conditions and atherosclerosis, which encompasses varicose veins (see Mayo Clinic sheets scope

of cardiovascular disease/conditions in the art) anticipating Claim 6 of the instant application.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

27. Claims 1-4, 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin (U.S. Pat. # 5604216).

Horrobin teaches a pharmaceutical and nutritional composition comprising cholesterol fatty acid ester in a suitable diluent or carrier. The cholesterol fatty acid esters taught include those formed from eicosapentaenoic acid. Horrobin teaches that the ester forms are desirable as they are usually stable and resistant to oxidation compared to the fatty acids themselves, salts, or triglyceride forms. Horrobin teaches that fatty acids including EPA have therapeutic value in a number of disorders specifically addressing the cardiovascular system and peripheral arterial disease which encompasses varicose veins (see Mayo Clinic sheets scope of cardiovascular disease/conditions in the art).

Horrobin teaches that the significance is in the context of delivering these fatty acids by administering the in the form of esters for the treatment of any of the disclosed conditions and any other disease. Horrobin teaches the synthesis of the esters and that they can be administered orally, topically parenterally, and any other appropriate route. The forms included tablets, capsules, emulsions, other pharmaceutical dosage forms, foods, and skin care preparations (cosmetics). The doses for oral administration are preferably form 500mg to 10g of the cholesterol ester per day. (Abstract, Col. 1, lines

10-30, Col. 2, lines 18-27, 37-65, 68, Col. 3, lines 1-4, 35-61, Col. 5, lines 25—45, Col. 6, Example 3, lines 55-68, Col. 7, lines 5-14, 25-45, Claims 1,2, and 9).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Response to Arguments

28. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Yazawa et al (EP 0,404,300).

Applicant's arguments filed 09/04/2007 on page 5 have been fully considered but they are not persuasive. Applicant's arguments against the prior art rejections of record are centered on the disclosure of varicose veins of lower extremities, and the negative recitation of phospholipids in the newly amended claims.

This is not persuasive as claim 5 is cancelled and claims 1-3 are composition claims where a recitation of intended use only requires that the prior art is *capable* of the intended use but does not need to recite it as that would be a method claim, not a composition claim.

Applicant argues that Yazawa would not apply with the amended negative recitation of phospholipids in the claims. This is not persuasive because as noted above that the claims as amended are in Markush language will be interpreted as so thereby, the composition would not contain any *one* of elements selected from the *group consisting of* "phospholipids, compounds which are a factor in methionine metabolism, and 10-40% by weight of antioxidant/reducing vitamins or provitamins". As a result, wherein a composition would contain phospholipids but not 10-40% by weight of

antioxidant/reducing vitamins or provitamins; or a composition would not contain phospholipids but did have 10-40% by weight of antioxidant/reducing vitamins or provitamins, it would fulfill the limitations of the claims as written.

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Yazawa et al (EP 0,404,300) is maintained.

29. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 01/84961).

Applicant's arguments, see on pages 5-6, filed 09/04/2007, have been fully considered and are not persuasive. Applicant's arguments against the prior art rejections of record are centered on the negative recitation of phospholipids or compounds which are a factor in methionine metabolism in the newly amended claims, data to show effectiveness in preventing and treating varicose veins, and that the instant invention is distinctive by comprising EPA as the effective component for treating varicose veins of human lower extremities.

This is not persuasive as claims 1-3 are composition claims where a recitation of intended use only requires that the prior art is *capable* of the intended use but does not need to recite it as that would be a method claim, not a composition claim.

Applicant argues that Kiliaan would not apply with the amended negative recitation of phospholipids or compounds, which are a factor in methionine metabolism in the claims. This is not persuasive because as noted above that the claims as amended are in Markush language will be interpreted as so thereby, the composition would not contain any *one* of elements selected from the *group consisting of*

"phospholipids, compounds which are a factor in methionine metabolism, and 10-40% by weight of antioxidant/reducing vitamins or provitamins". As a result, wherein a composition would contain phospholipids but not 10-40% by weight of antioxidant/reducing vitamins or provitamins; or a composition would not contain phospholipids but did have 10-40% by weight of antioxidant/reducing vitamins or provitamins, it would fulfill the limitations of the claims as written.

These arguments are not persuasive with respect to claim 6 as Kiliaan does teach the compositions and their use for treatment of vascular, cardio-and cerebrovascular disorders and the specific cardiovascular problems that were addressed were limited and included thrombi, vascular accidents, atherosclerosis, and varicose veins/varices which are included in their claims (Page 11, lines 28-30, Page 12, lines 9-14, claims 15-16). One of skill in the art would have a reasonable expectation of success with this teaching. The argument of the term "prevention" has been addressed in the previous action.

In terms of distinctiveness of the instant invention, the term comprising is open language whereby EPA an effective component but not the sole component for treating varicose veins of human lower extremities. Thereby the argument is not persuasive.

With respect to claim 6, the amendment to specifying the dose to 0.1 to 9g per day is still currently taught by the art. Kiliaan teaches the daily dose of the preparation in particular contains at least 50mg of EPA and preferably 50 to 1000mg. The capsule of Example 1 has a daily dose of 225mg, and Example 3 is for a drink that can by a milk drink. The USDA Food Guide Pyramid (see Healthy Eating Based on the Food Guide

Pyramid) lists 2-4 servings a day so an average of 3 to 4 serving a day of the composition would provide about 0.9 to about 1.2g of EPA a day, fulfilling the claim.

The rejection of claims 1-3 and 6 under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 01/84961) is maintained.

30. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruzzese (U.S. Pat. # 5,776,978).

Applicant's arguments, see on pages 6-7, filed 09/04/2007, have been fully considered and are not persuasive. Applicant's arguments against the prior art rejections of record are centered on the negative recitation of 10-40% by weight of antioxidant/reducing vitamins or provitamins in the newly amended claims, data to show suppression of varicose veins, and that the instant invention is distinctive by comprising EPA as the effective component for treating varicose veins of human lower extremities.

This is not persuasive as claims 1-4 are composition claims where a recitation of intended use only requires that the prior art is *capable* of the intended use but does not need to recite it as that would be a method claim, not a composition claim.

Bruzzese teaches compositions comprised of EPA esters or EPA ethylesters. Bruzzese also taught the use of these compositions for cardiovascular conditions and atherosclerosis, which encompasses varicose veins (see Mayo Clinic sheets scope of cardiovascular disease/conditions in the art) anticipating Claim 6 of the instant application. One of skill in the art would have a reasonable expectation of success with this teaching.

In terms of distinctiveness of the instant invention, the term comprising is open language whereby EPA an effective component but not the sole component for treating varicose veins of human lower extremities. Thereby the argument is not persuasive.

Applicant argues that Bruzzese would not apply with the amended negative recitation of 10-40% by weight of antioxidant/reducing vitamins or provitamins in the claims. This is not persuasive because as noted above that the claims as amended are in Markush language will be interpreted as so thereby, the composition would not contain any *one* of elements selected from the *group consisting of* "phospholipids, compounds which are a factor in methionine metabolism, and 10-40% by weight of antioxidant/reducing vitamins or provitamins". As a result, wherein a composition would contain phospholipids but not 10-40% by weight of antioxidant/reducing vitamins or provitamins; or a composition would not contain phospholipids but did have 10-40% by weight of antioxidant/reducing vitamins or provitamins, it would fulfill the limitations of the claims as written.

With respect to claim 6, the amendment to specifying the dose to 0.1 to 9g per day is still currently taught by the art. Bruzzese teaches in Groups 4 and 5 (Col. 3) 25mg/kg of an EPA+DHA ester mixture with ratios of (1:1 and 30:100 respectively) and the average weight of an adult male is 81.57kg and an adult female is 68.87kg (see The validity of self-reported...). This results in a daily dose of the preparation of 8.66g males/7.32g females (Group 4) and 4.71kg males/3.97g females (Group 5), fulfilling the claim.

31. The rejection of claims 1-3 and 6 under 35 U.S.C. 102(b) as being anticipated by Bruzzese (U.S. Pat. # 5,776,978) is maintained.

Conclusion

32. Claims 1-4 and 6-11 are rejected.

33. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

/Zohreh Fay/ (Primary Examiner)